DEPARTMENT OF HEALTH & HUMAN SERVICES

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-29

August 29, 2001

Robert R. Dixon, President
Dixon Fisheries, Inc.
1807 North Main Street
East Peoria, IL 61611

Dear Mr. Dixon:

On April 2nd thru 6th, 2001, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 2840 Fortune Circle East, Suite A, Indianapolis, IN. The inspection was conducted to determine compliance with the FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulation (21 CFR 123) and the current Good Manufacturing Practice requirements for foods (GMP) (21 CFR 110).

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator presented your firm with a form FDA-483 that provides the investigator evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. In spite of some of the corrections you have made, we still find your firm is in violation of 21 CFR 123 and 110 causing your products to be deemed adulterated under the provisions of 21 U.S.C. 342(a)(4) because of the following:

1. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at your critical control points to control

the hazards listed in your HACCP plans for Fresh Scombroid Fish, Pasteurized Crabmeat, Molluscan Shellfish, and Fresh Ready-to-Eat Products. Your firm failed to keep monitoring records documenting your observations, corrective actions, and verification procedures at your critical control points for several months.

2. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plans for "Ready-to-Eat Products and Molluscan Shellfish list a critical limit of the cooler temperature not to exceed 40°F for more than 4 hours in any 24 hour period and cooler temperature not to exceed 50°F which is not adequate to control the pathogen growth hazard.

   Your HACCP plans list two conflicting critical limits at the Cooler Storage critical control point. Since your plan covers a variety of products, your critical limit must be set at an appropriate temperature to control the pathogen that is most tolerant of cool temperatures and associated with your products. If any of the refrigerated items listed are packaged in oxygen limiting packaging, FDA suggests you select Clostridium botulinum as your target pathogen and list your critical limit as 37.9° degrees Fahrenheit.

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the protection of food, food packaging materials, and food contact surfaces from adulteration as evidenced by our investigator's observation of your employees failing to wash their hands before returning to their work stations and an employee's failure to wear an appropriate hair restraint (beard net) while working with exposed products.

   You must maintain sanitation control records to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control monitoring records from 1/25/01 through 4/2/01.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to Greta L. Budweg, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone (313) 226-6260 ext. 107.

Sincerely,

Raymond V. Mlecko
District Director
Detroit District

cc: Kevin R. Boley, Processing Manager
Dixon Fisheries, Inc.
2840 Fortune Circle East, Suite A
Indianapolis, IN 46241

Encl.